## Claims

1. Substantially purified Tumor Necrosis Factor (TNF) Binding Protein-II, herein designated TBP-II, salts, functional derivatives, precursors and active fractions thereof and mixtures of any of the foregoing, having the ability to inhibit the cytotoxic effect of TNF and/or to maintain its prolonged beneficial effects.

2. The substantially purified TNF Binding Protein TBP-II of claim 1.

3. The TNF Binding Protein TBP-II of claim 1 having a molecular weight of about 30 kDa when the substantially purified protein is analyzed by SDS-PAGE under reducing conditions.

4. The TNF Binding Protein TBP-II of claim 1 moving as a single peak on reversed-phase high performance liquid chromatography (HPLC).

5. The TNF Binding Protein TBP-II of claim 1 having the ability to inhibit the cytotoxic effect of TNF-α on murine A9 cells.

6. The TNF Binding Protein TBP-II of claim 1 which contains the following amino acid sequence obtained by N-terminal analysis:
Ala-Gln-Val-Ala-Phe-Thr-Pro-Tyr-Ala-Pro-Glu-Pro-Gly-Ser-Thr-Cys-Arg-Leu-Arg-Glu-Tyr-Tyr-Asp-Gln-Thr-Ala-Gln-Met-Cys-Cys-
or a truncated form thereof.

7. A process for the production of substantially purified TBP-II Protein which comprises:

(a) recovering the crude protein fraction from a dyalized concentrate of human urine;

(b) subjecting said crude protein fraction of step (a) to affinity chromatography on a column of immobilized TNF to obtain purified active fractions of TNF Binding Proteins defined by their ability to inhibit the cytotoxic effect of TNF;

(c) applying said purified active fractions of the TNF Binding Proteins from step (b) to reversed-phase high pressure liquid chromatography (HPLC) to obtain substantially purified active fractions of TNF Binding Proteins defined by their ability to inhibit the cytotoxic effect of TNF; and

(d) recovering the substantially purified TBP-II protein of step (c), said protein having a molecular weight of about 30 kD on SDS PAGE under reducing conditions, moving as a single peak in the fraction corresponding to about 31% acetonitrile on reversed-phase HPLC and having the ability to inhibit the cytotoxic effect of TNF.

8. The TNF Binding Protein TBP-II according to claim 1 produced by the process of claim 7.

9. The human TNF Binding Protein TBP-II of claim 1.

10. The TNF Binding Protein TBP-II of claim 1 which is a recombinant protein.

11. A DNA molecule comprising the nucleotide sequence coding for the TNF Binding Protein TBP-II of claim 1 or to a protein homolog therewith.

12. A replicable expression vehicle comprising the DNA molecule of claim 11 and capable, in a transformant host cell, of expressing the TNF Binding Protein TBP-II of claim 1.

13. A host cell selected from the group consisting of a prokaryotic and a eukaryotic cell transformed with the replicable expression vehicle of claim 12.

14. A process for producing TNF Binding Protein TBP-II comprising the steps of: (a) culturing a transformant host cell according to claim 13 in a suitable culture medium, and (b) isolating said TNF Binding Protein TBP-II.

15. A pharmaceutical composition comprising TNF Binding Protein TBP-II and/or salts, functional derivatives, precursors or active fractions thereof and mixtures of any of the foregoing, as active ingredient together with a pharmaceutically acceptable carrier.

16. A method for treating conditions wherein TNF, either endogenously formed or exogenously administered, is to be eliminated from the body or its effect in the body is to be antagonized which comprises administering to a patient in need of such treatment, an amount of an agent selected from the TNF Binding Protein TBP-II of claim1, salts, functional derivatives, precursors or active fractions thereof, and mixtures of any of the foregoing, or a pharmaceutical composition comprising them, said amount

being effective to antagonize the deleterious effect of TNF.

17. A method for treating conditions wherein TNF beneficial effects are to be maintained and prolonged, which comprises administering to a patient in need of such treatment a mixture of TNF and an amount of TBP-II, salts, functional derivatives, precursors or active fractions thereof or mixtures of any of the foregoing, said amount being effective to maintain such prolonged beneficial effect of TNF.

18. An antibody to human TNF Binding Protein TBP-II which specifically recognizes said protein.

19. An antibody as claimed in claim 18 which is further characterized in that it blocks the binding of TNF to U937 and K562 cells.

20. An antibody as claimed in claim 18 further characterized in that it does not block the binding of TNF to HeLa and MCF7 cells.

21. An antibody according to claim 18 which is a polyclonal antibody.

22. An antibody according to claim 18 which is a monoclonal antibody.

23. A monoclonal antibody according to claim 22 produced from a hybridoma formed by fusion of myeloma cells with spleen cells and lymphocytes of mice previously immunized with TBP-II.

24. A monoclonal antibody according to claim 23 produced from hybridoma TBP-II 13-12 deposited in CNCM under designation I-929.

25. A monoclonal antibody according to claim 23 produced from hybridoma TBP-II 70-2, deposited in CNCM under designation I-928.

26. Pharmaceutical compositions comprising an antibody according to claim 18 or F(ab) fragments thereof or salts, functional derivatives or active fractions of the antibody or of the fragment thereof, for blocking the binding of TNF to, and inhibiting its effect on cells.

27. Pharmaceutical compositions comprising an antibody according to claim 18 or F(ab) fragments thereof or salts, functional derivatives or active fractions of the antibody or of the fragment thereof, for the treatment of conditions wherein effects of TNF, either endogenously formed or exogenously administered, are to be antagonized.

28. Pharmaceutical compositions comprising an antibody according to claim 18 or F(ab) fragments thereof or salts, functional derivatives or active fractions of the antibody or of the fragment thereof, for mimicking beneficial effects of TNF on cells.

29. Pharmaceutical compositions comprising an antibody according to claim 18 or F(ab) fragments thereof or salts, functional derivatives or active fractions of the antibody or of the fragment thereof for mimicking the cytotoxic effect of TNF.

30. An immunoassay for the TNF Binding Protein TBP-II in body fluids characterized by measuring its interaction with an antibody according to claim 18.

31. A diagnostic assay for measuring the levels of antibodies to TBP-II endogenously produced in sera of patients in several disorders, e.g., autoimmune diseases, characterized by measuring the interaction of endogenous antibody with TBP-II.

32. A method for the purification of human TNF Binding Protein TBP-II utilizing a suitable antibody according to claim 18 comprising the following steps:

a. coupling said antibody to a suitable resin to construct an immunoaffinity column;

b. loading a solution containing said protein on said immunoaffinity column;

c. washing away the non-bound proteins with a suitable washing buffer;

d. eluting the bound TNF Binding Protein TBP-II with a suitable eluent; and

e. collecting the enriched fraction of said TBP-II.